

# **American Society of Transplant Surgeons**

January 18, 2013

The Honorable Barbara Boxer U.S. Senate

The Honorable Tom Coburn U. S. Senate

The Honorable Lois Capps U.S. House of Representatives

# Re: Support for Safe and Timely Access to Transplantation Act of 2013: The "STAT" Act

Dear Senators Boxer and Coburn, and Representative Capps:

The American Society of Transplant Surgeons (ASTS) would like to express its support for your legislation to amend the Public Health Service Act to establish safeguards and standards of quality for research and transplantation of organs infected with human immunodeficiency virus (HIV). We applaud your efforts in introducing the Safe and Timely Access to Transplantation Act of 2013 (the "STAT" Act) and look forward to working with you to achieve enactment of this important legislation.

ASTS is a medical specialty society comprised of over 2000 transplant surgeons, physicians, scientists, advanced transplant providers and allied health professionals dedicated to excellence in transplant surgery through education and research with respect to all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure.

ASTS has long been committed to policies that increase the pool of available organs for transplant. More than 8,000 people die each year waiting for a suitable organ to become available and the waiting list for donor organs continues to grow well past 100,000 people. The STAT Act would remove the current legal ban on the use of HIV-positive organs for HIV-positive individuals in need of a donor organ. The law's restriction, originally enacted in 1988, has been eclipsed by advances in HIV treatment and is simply not supportable in contemporary medicine.

The STAT Act will provide HIV infected organs to HIV infected recipients, thereby saving lives and improving the quality of life of these individuals. Under current law, these organs are simply discarded while the transplant waiting list continues to grow. Not only will passage of this legislation increase access to life-saving transplants for this population, but it will allow the scientific and transplant community to conduct much needed research in this area.

The legislation also calls for regulations to be issued by the Secretary of Health and Human Services within one year of enactment. These regulations are intended to establish clear guidelines and standards for clinical research that will help ensure that recipients, donors, and the public are protected. ASTS strongly supports this

National Office 2461 South Clark Street Suite 640 Arlington, VA 22202 Phone: 703 414-7870 Fax: 703 414-7874 asts@asts.org www.ASTS.org

#### President

Kim M. Olthoff, MD University of Pennsylvania Department of Surgery 3400 Spruce Street - 2 Dulles Philadelphia, PA 19104 Phone: 215 662-6136 Fax: 215 662-2244 kim.olthoff@uphs.upenn.edu

### President-Elect

Alan N. Langnas, DO University of Nebraska 983285 Nebraska Medical Center Omaha, NE 68198-3285 Phone: 402 559-8390 Fax: 402 559-3434 alangnas@unmc.edu

#### Secretary

Charles M. Miller, MD Cleveland Clinic Foundation 9500 Euclid Ave. Mail Code A-110 Cleveland, OH 44195 Phone: 216 445-2381 Fax: 216 444-9375 millerc8@ccf.org

#### Treasurer

Timothy L. Pruett, MD University of Minnesota Department of Surgery 420 Delaware Street SE MMC 195 Minneapolis, MN 55455

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Executive Director Kimberly Gifford, MBA Kim.gifford@asts.org provision and believes this regulatory process should emphasize the development of standards to protect against unintended HIV transmission. It is critical to prevent even the most remote chance that a non-HIV infected individual will inadvertently receive an HIV-infected organ. Transplantation of an HIV-infected organ into a non-HIV infected patient would be potentially devastating to the recipient, would undermine public trust in the transplantation process and could actually cause decreased organ donation. The regulations should specifically aim to make inadvertent transmission as close to a "never event" as possible and erect effective safeguards for proper identification, transport and transplant of HIV-infected organs and accompanying blood vessels.

ASTS greatly appreciates your efforts to expand the supply of life-saving organs for HIV positive individuals and we appreciate your leadership in moving the STAT Act forward. If you have any questions, or if we can be of any assistance to you, please do not hesitate to contact me or our Legislative Counsel, Peter Thomas at (202) 466-6550 or <a href="mailto:peter.thomas@ppsv.com">peter.thomas@ppsv.com</a>.

Best regards,

Kim Olthoff, MD

President